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| 09/837,714 | 04/18/2001 | Daniel A. Japuntich | 48317USA3M.032 | 9172 | |
| | 7590 12/28/200 IVE PROPERTIES CO | EXAMINER | | | |
| PO BOX 33427 | | | BRANDT, ADAM CURTIS | | |
| ST. PAUL, MN | I 55133-3427 | | ART UNIT PAPER NUMBER | | |
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| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| - <u></u> | Application No. | Applicant(s) | | |
|---|---|--|--|--|
| | 09/837,714 | JAPUNTICH ET AL. | | |
| Office Action Summary | Examiner | Art Unit | | |
| · | Adam Brandt | 3771 | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D. (35 U.S.C. § 133) | | |
| Status | | | | |
| Responsive to communication(s) filed on <u>05 Oct</u> This action is FINAL . 2b) ☐ This Since this application is in condition for allowant closed in accordance with the practice under <i>E</i> . | action is non-final. nce except for formal matters, pro | | | |
| Disposition of Claims | | | | |
| 4) | vn from consideration. 6 is/are rejected. | 1. | | |
| Application Papers | | | | |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on 18 April 2001 is/are: a) Applicant may not request that any objection to the or Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examiner | ☐ accepted or b)☐ objected to be drawing(s) be held in abeyance. See on is required if the drawing(s) is obj | e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| Attachment(s) | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/5/2006 | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa | te | | |

DETAILED ACTION

1. This action is in response to the amendment filed on 10/05/2006. Presently claims 33, 35-42, 44, 46, 49, 50, 55-59, and 64-66 are pending in the application.

Information Disclosure Statement

2. This office acknowledges receipt of the following items from the applicant: Information Disclosure Statement (IDS) filed 10/5/2006. The references cited on the PTO 1449 form have been considered.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 31 and 59. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Specification

4. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

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6. The abstract of the disclosure is objected to because it is over the maximum of 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 33,39,40,44,46,49,50,55-59,64,65 rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of Cover ('183) and Soderberg (EP 0 252 890).

As to claim 33, Simpson et al. disclose a method of making a filtering face mask which method comprises: providing a valve seat that comprises an orifice (16) and a seal surface, wherein the orifice allows exhaled air to pass through and being surrounded by the seal surface; and a single flexible flap (15), supporting the single flexible flap non-centrally and operatively relative to the orifice of the valve seat to form an exhalation valve and attaching the exhalation valve to the mask body that is adapted to fit over the nose and mouth of a person (fig.1).

The differences between Simpson et al. and claim 33 are supporting the single flexible flap such that the flap assumes, in its closed state, a curved profile in a cross-sectional view thereof, which the curved profile comprises a curve that extends from a first point where a first stationary portion of the flexible flap is supported on the valve seat to a second point where a second free portion of the flap is pressed against the seal surface of the valve seat in a closed state of the exhalation valve, and the second free portion of the flexible flap is held in its closed

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state under any orientation of the valve, at least in part, by virtue of the curved profile thereof; and the second free portion of the flexible flap represents the only free portion of the flap and can flex so as to permit exhaled air to pass through the orifice and to provide an open state of the exhalation valve to make the flexible flap out of contact with the seal surface at the second point while the first portion of the flexible flap remains essentially stationary at the first point.

Cover (page 2, col.1, lines 3-6, lines 15-17, lines 22-33, lines 48-51) teaches supporting the single flexible flap (23) such that the flap assumes, in its closed state, a curved profile in a cross-sectional view thereof (figs.1,2,4), which the curved profile comprises a curve that extends from a first point (21,25,26) where a first stationary portion of the flexible flap is supported on the valve seat to a second point where a second free portion of the flap is pressed against the seal surface of the valve seat in a closed state of the exhalation valve, and the second free portion of the flexible flap is held in its closed state under any orientation of the valve, at least in part, by virtue of the curved profile thereof; and the second free portion of the flexible flap represents the only free portion of the flap and can flex so as to permit exhaled air to pass (page 2, col.1, lines 44-48) through the orifice and to provide an open state of the exhalation valve to make the flexible flap out of contact with the seal surface at the second point while the first portion of the flexible flap remains essentially stationary at the first point. Cover teaches this valve configuration for the purpose of improving the closing action of the valve flap, improving the retention of the valve flap in effective registration with the apertures of the valve seat and causing the valve flap to function more efficiently.

It would have been obvious to modify the shape of the valve seat of Simpson et al. to have a curved profile when viewed from a side elevation because it would have improved the

closing action of the valve flap, improved the retention of the valve flap in effective registration with the apertures of the valve seat and caused the valve flap to function more efficiently as taught by Cover.

To the extent, if any, that the valve flap of Simpson et al. as modified by Cover may not be held in its closed state under any orientation of the valve, at least in part, by virtue of the curved profile, resort is had to Soderberg (page 4, lines 13-23) which teach a rubber valve membrane having a beveled edge (12) that will seal against the valve seat (3) irrespective of position assumed by the valve device. It would have been obvious to further modify the edge of the valve membrane of Simpson et al. to include a beveled edge to aid in maintaining a seal with the valve seat under any orientation of the valve device as taught by Soderberg.

As to claims 39 and 40, the flap retaining surface of Simpson et al. (fig.2) is illustrated as being positioned adjacent one side of the orifice (16) and is oriented transversely (i.e. inasmuch as the retaining surface extends across one side of the orifice) relative to the orifice (16).

As to claim 44, the shape of the orifice (16) of Simpson et al. does not fully correspond to the shape of the seal surface and the flexible flap (15) is mounted to the valve seat in cantilever fashion.

As to claim 46, the curvature of the flexible flap of Simpson et al. as modified by Cover extends from a plurality of points where the flap is affixed to the valve seat to a plurality of points which are opposite the plurality of points on the fixed portion of the flexible flap (e.g. figs. 1,2,4 of Cover).

As to claim 49, the relative dimensions and spacing of the constituents of the exhalation valve of Simpson et al. can be arrived at through mere routine obvious experimentation and

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observation with no criticality seen in any particular relative spacing including 1-3.5 mm between the flap retaining surface and the orifice because of the use of different sizes of valves in an effort to accommodate different sized wearers.

As to claim 50, the particular material from which the valve seat of Simpson et al. is made and the manner of making the valve seat can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material including a relatively light weight plastic. Inasmuch as Simpson et al. (page 2, lines 37-65) disclose the valve flap being made from plastic and/or rubber material, it would have been obvious to make the valve seat from any well known material which would achieve known or expected results including a plastic and/or rubber material because the use of a valve seat of the same material as the valve flap would have provided for more effective physically cooperation.

As to claim 56, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency.

As to claim 55, the second free portion of the flexible flap of Simpson et al. as modified by Cover has a profile that when viewed from the front corresponds to the general shape of the seal surface and comprises a curve (figs.1,2,4 of Cover).

As to claim 57, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation

with no criticality seen in any particular relative amounts including 10-25% fixed and 75-90% free.

As to claim 58, the flexible flap of Simpson et al. is positioned on the valve such that exhaled air deflected downward during an exhalation when the filtering facemask is worn on a person (fig.1 of Simpson et al.).

As to claim 59, Simpson et al. (page 1, lines 116-123) disclose the mask body is cupshaped and comprises at least one shaping layer for providing structure to the mask, and a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

As to claim 64, the exhalation valve of Simpson et al. (fig.1) is positioned on the mask body substantially opposite to a wearer's mouth and such that the second free portion of the flexible flap resides beneath the stationary portion when the mask is worn on a person.

New claims 65 and 66 are substantially equivalent in scope to claim 33 and are included in Simpson et al. as modified by Cover for the reasons set forth above with respect to claim 33.

9. Claims 35-38,41,42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of Cover ('183) and Soderberg (EP 0 252 890) as applied to claims 33,39,40,44,46,49,50,55-59,64,65 above, and further in view of Shindel ('277).

The difference between Simpson et al. as modified by Cover and claim 35 is securing a valve cover to the valve seat, wherein the valve seat includes a flap-retaining surface, and the flap-retaining surface is located within an internal chamber defined by the valve cover.

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Shindel (col.2, lines 59-66) teaches a valve securing device in the form of a valve cover (7) that is disposed over the valve seat and that comprises a surface (14) that mechanically holds flexible flap (6) against the flap retaining surface (5) in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve, the point where the flexible flap is mechanically held against the flap retaining surface being located off center (fig.2) relative to the flap. Shindel cites the advantages of simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices.

It would have been obvious to further modify the manner of attachment of the exhalation valve of Simpson et al. to employ a cover over the valve seat because it would have provided a simple arrangement with ready removability of the cover when desired and because it would have provided protection for the exhalation valve as taught by Shindel.

As to claim 42, the flexible flap of Simpson et al. as modified by Cover (page 1, col.2, lines 41-43 and figs.1,2,4) would normally assume a flat configuration (Cover expressly discloses the valve flap 23 is formed from a thin sheet of flexible and resilient rubber material) but is curved by virtue of its securement of the flap to the valve seat and the relative positioning and alignment between the seal surface and the flap retaining surface.

As to claims 36 and 37, the first stationary portion of the flexible flap of Simpson et al. as further modified by Shindel is held (via mechanical clamping) between the flap retaining surface (#5 of Shindel) on the valve seat and a second member (#14,15 of Shindel) that is associated with the valve cover when the valve cover is secured to the valve seat.

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As to claim 38, the flexible flap of Simpson et al. as modified by Cover (figs.1,2,4) and Shindel teaches that the flexible flap can assume a curved profile, when in its closed state, that extends in from where the flexible flap contacts the second member (#5 of Shindel) of the valve cover to where the second portion of the flexible flap contacts the seal surface of the valve seat.

As to claim 41, the flexible flap of Simpson et al. as modified by Cover (page 1, col.2, lines 41-43 and figs.1,2,4) would normally assume a flat configuration (Cover expressly discloses the valve flap 23 is formed from a thin sheet of flexible and resilient rubber material) but is curved by virtue of its securement of the flap to the valve seat and the relative positioning and alignment between the seal surface and the flap retaining surface.

Response to Arguments

7. Applicant's arguments filed 10/5/2006 have been fully considered but they are not persuasive.

The Applicant argues that Simpson et al. (GB 2 072 516) does not disclose a flap that is curved when secured to the valve seat. Applicant further argues that Simpson et al.'s flap does not seal itself in any orientation unless assisted by gravity.

The Examiner agrees with the Applicant that the flap is not curved, but Cover (2,105,183) teaches that it well known in the art to use curved flaps. The patent to Cover teaches that a single movable element (23) with a rigid base plate (17) forms a single flap valve shaped in a concave form (page 2, column 1, lines 3-7). This Simpson et al.'s facemask when modified with Cover's flap meets the limitation set forth in the claim.

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In response to flap's ability to seal appropriately, the Examiner reasons that the purpose of Simpson et al.'s respiratory facemask is to effectively filter undesired particles from entering the body. The valve is inherently closed during inhalation and open during exhalation. The operation of the valve is questionable in between inhalation and exhalation phases. Unless assisted by gravity, which is the configuration presented by Simpson et al., the valve may not seal properly. The limitations set forth in the claim require the second free portion of the flap to be in contact with the valve seat in any physical orientation when the valve is closed; secondly, the first portion must remain stationary while the second free portion is permitted to releasably contact the seal as to permit air to pass through the orifice. In regards to the first limitation presented above, it is inherent that when Cover's valve is in the closed position, it will be in contact with the valve seat. Otherwise, the valve in the closed position would not be closed at all but instead open allowing fluid to pass. In regards to the second limitation presented above, the first portion (21,25,26) is stationary and supported on the valve seal as seen in figures 1, 2, and 4. The second free portion is pressed against the seal surface of the valve seat in the closed exhalation valve. Therefore, Simpson modified by Cover meets these limitations as presented previously in the rejection above.

The Applicant argues that the mounting hardware interferes with the fluid flow of the valve. When any material is placed in line or adjacent with the flow path of a fluid it will cause resistance. No more resistance will result from the surrounding mounting hardware than would be expected to occur from occlusion cause by the curved flap or the surrounding walls of the Applicant's invention. Therefore it is does not prevent the modified device of Simpson et al. from performing properly.

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The Applicant argues that Cover does not teach a single flap but instead a double flap system. Cover teaches that a single movable element (23) with a rigid base plate (17) forms a single flap valve shaped in a concave form (page 2, column 1, lines 3-7).

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The Applicant argues that Soderberg (EP 0 252 890) teaches a flexible flap for sealing the exhalation valve, but achieves these results using a beveled edge which does not meet the limitations of the claim. The Soderberg reference was provided because it is believed that Simpson et al. and Cover combine to meet the limitations of the claim, but fail to meet the limitation that through all orientations the flap will be held in its closed state. Soderberg teaches that is well known to hold the flap closed unless influenced (page 4, lines 12-13). Soderberg does not disclose a flap with a curved profile. As seen in figure 1, openings 5 and 6 and studs 14 are the attachment means which is similar to the pins used in the Applicant's invention in that there are apertures in the flap and a elongated restraining members to affix part of the flap. When modified with Cover, the references combine to meet the limitations of the claim.

In response to applicant's argument based upon the age of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

The facemask as taught by Simpson et al. modified with the flap of Cover and further modified with the teaching of Soderberg meet the limitation of the claims. The claims stand as rejected.

Conclusion

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ACB ACB

TEENA MITCHELL
PRIMARY EXAMINER

Adam Brandt Examiner Art Unit 3771

Adam Brandt